

Because these documents were earlier filed in a timely manner, Applicants respectfully submit that no fee is due for their consideration. However, in the event a fee is due for their consideration, authorization is given for charging deposit account 20-0531 for that fee. If other action is required for these references to be considered, the undersigned attorney invites the Examiner to call him at the telephone number listed below.

Rejection under 35 U.S.C. § 103(a)

Claims 19-24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over International Patent Application Publication Serial Number WO 97/09090 ("Barnett"). Independent claim 19 recites, in part, a seal comprising a bladder filled with a molded material having a durometer value less than about ten on a Shore 000 scale.

Barnett teaches away from using a material having a durometer value of less than about ten on a Shore 000 scale. More specifically, Barnett discloses that the facial seal 18 has a resiliency, as defined by durometer measured on the Shore 00 scale, of about 10 or softer and, most preferably, about 0. Barnett, page 10, lines 2-6. Barnett reports that such resiliency corresponds substantially to that of human fat tissue. Barnett, page 10, lines 6-9. It is emphasized, however, that the facial seal must exhibit some measurable recoil memory. Barnett, page 10, lines 33-34. Barnett teaches that to achieve recoil memory and other properties, the annular member is formed from a gel substance that, while purportedly virtually indistinguishable from human fat tissue when measured on Shore 00 scale, exhibits a resiliency or durometer on the Shore 000 scale of from about 20 to about 45. Barnett, page 11, lines 5-13. Barnett specifically contrasts the substance with human fat tissue which registers a durometer of about 10 on the Shore 000 scale. Barnett, page 11, lines 13-15. More specifically, Barnett states, at page 10, lines 21-33:

[A]ny respiratory mask facial seal possessing structural characteristics essentially identical to fat would be impractical from a usage standpoint. That is, if a facial seal were fabricated from a material structurally indistinguishable from human fat tissue in terms of resiliency, it may tend to sag into an amorphous shape under the influence of gravity and thus would not effectively conform to the contours of a user's face even if headstrap tension was quite high. It will be appreciated, therefore, that a properly designed facial seal must substantially but not identically mimic human fat tissue from a structural, particularly resiliency, perspective.

Barnett, thus, teaches a skilled artisan not to use soft material of less than about 20 on the Shore 000 scale, and expressly teaches away from using a soft material having a durometer value of less than about ten on a Shore 000 scale, because it "would be impractical...."

Accordingly, Applicants respectfully submit that Barnett teaches away from a material having a durometer value of less than about ten on a Shore 000 scale and that claim 19 is patentable over Barnett. Claims 20-29, which depend either directly or indirectly from an allowable base claim, also are allowable. In light of the foregoing, reconsideration and withdrawal of this rejection, and issuance of a Notice of Allowance for claims 19-29, are respectfully requested.

Respectfully submitted,

Date: April 1, 2002
Reg. No. 45,508

Tel. No.: (617) 248-7226
Fax No.: (617) 248-7100
2302610-1



Daniel A. Wilson
Attorney for the Applicants
Testa, Hurwitz, & Thibeault, LLP
High Street Tower
125 High Street
Boston, Massachusetts 02110

Marked-up Version of Specification for U.S.S.N. 09/328,120

As stated hereinabove, according to one embodiment, the seal fill material has a durometer value of less than about ten on the Shore or Type OOO scale. Such low durometer values on this scale can be measured using apparatus and test methodology generally in accordance with Type A, B, C, D, DO, O, OO durometer test method of American Society for Testing and Materials (ASTM) Designation D 2240-97^{E1}: Standard Test Method for Rubber Property – Durometer Hardness, approved February 10, 1997 [1995], and revised editorially in February 1999. As is known by those skilled in the art of testing the durometer of ultrasoft gels and sponge rubber on the Shore OOO scale, a 0.5 inch hemispherical end indenter shape is used in combination with a 113 gram-force main spring.

Marked-up Version of New Claims for U.S.S.N. 09/328,120

25. (New) The seal of claim 19 wherein the seal is about 0.225 inches thick.
26. (New) The seal of claim 19 wherein the seal comprises a generally oval shape.
27. (New) The seal of claim 19 wherein the seal comprises a concave area.
28. (New) The seal of claim 19 wherein the seal comprises a convex arc.
29. (New) The seal of claim 19 wherein the seal comprises a variable thickness.